Proposed & Current NJ Requirements Related to Patient Safety

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Current NJ law needs improvement to promote patient safety

- No protection from discovery of peer-review materials or reports to the State
  - Inhibits formal internal review of errors, due to litigation fears
    - Some reviews conducted without documentation
    - Others conducted under attorney-client privilege
  - Promotes a culture of silence instead of aggressive examination of errors and near-misses

Current NJ law needs improvement to promote patient safety

- No *explicit statutory* mandate to report errors to the State
  - Regulatory mandates often ignored – also due largely to litigation fears
    - State can protect from disclosure only personal health information of patients
  - Reporting rules part of a licensure system designed to handle individual cases, not develop systematic data
  - Result – State lacks data to conduct trend analysis and inform industry of statewide problems

Current Hospital Adverse Event Reporting Rules

N.J.A.C.8:43G-6.10, Anesthesia continuous quality improvement methods

- *What must be reported:* For patients classified as ASA Class IV or V, all deaths in anesthetizing locations (after administration of anesthesia) and unexpected intraoperative or postoperative events or outcomes related to anesthesia and occurring within 48 hours of administration of anesthesia.

Anesthesia Reporting Requirements

- *To whom reported:* DHSS
- *When:* within 24 hours by phone, and in writing within 30 days
- *Disclosure of information:* Personal health information of patients may not be disclosed to the public

Anesthesia Reporting Requirements

- Assessment of rule's effectiveness
  - Few hospitals report anything
  - Until 2003, reports were required on all patients, not just ASA Class IV or V
    - Vast majority of reports did not reflect errors
    - Staff overloaded and desensitized to the reports
  - Hospitals confused by separate rule for reportable events – how do the two relate?

Current Hospital Adverse Event Reporting Rules

N.J.A.C. 8:43G-5.6, Reportable events

- *What must be reported:* any event that jeopardizes the health and safety of patients or employees, including:
  - Unscheduled interruption (3 or more hours) of essential physical plant or clinical services
  - Fires, disasters or accidents leading to serious injury or death of patients or employees, or in evacuation of patients

Hospital Reportable Events

- All alleged or suspected crimes which endanger the life or safety of patients or employees

- In addition, DHSS interprets the rule to require reports of sentinel events
  - November, 2000 advised industry to report events roughly corresponding to JCAHO sentinel event definition
  - May, 2003, updated advice industry based on National Quality Forum's "never events" list

Hospital Reportable Events

- *To whom reported:* DHSS
- *When:* as soon as possible by phone, but no later than three hours after discovery; follow up written confirmation within 7 days
- *Disclosure of information:* Personal health information of patients may not be disclosed to the public

Hospital Reportable Events

- Assessment of rule's effectiveness
  - Prior to May, 2003 memo, majority of reports concerned minor events
    - Staff overloaded and desensitized to the reports
    - Since May fewer reports, but tending to cover more serious incidents
  - Compliance uneven but improving

How can NJ Promote Patient Safety?

- Change the law to create environment supporting improvements in patient safety

- Track and analyze data systematically, in addition to case-by-case licensure enforcement approach

Proposed Patient Safety Legislation

- Component of medical malpractice liability reform bills

- Separate bills proposed in Senate (S2174) and Assembly (A50) this year
  - As of July 1st, A50 substituted for S2174, but needs further action by Assembly

Overview
Proposed Patient Safety Legislation

- DHSS worked closely with Senate to develop patient safety provisions in S2174

- Some key differences from A50

Patient Safety Preamble
(in S2174 only)

- Majority of medical errors result from complex systems problems, not individual incompetence;
- Key component of successful patient safety strategy is feedback mechanism to detect, analyze and correct for adverse events and "near-misses"

Patient Safety Preamble

- Critical need to create non-punitive culture focused on improving processes in the complex systems of care
- Health care facilities and professionals must be held accountable for serious errors
- But exclusive emphasis on assigning blame/liability deters free exchange of information and analyses of errors

Provisions found in both bills

Extension of Good Samaritan Protections

- Intent: reduce fear of litigation as barrier to professionals helping out in emergencies within health care facilities
- Protects health professionals responding to a life-threatening emergency inside a facility

Good Samaritan Provisions

- Does not apply if professional's duties include emergency response; is on-call; has a provider-patient relationship; or receives compensation for the emergency service
  - Under A50 also does not apply if ED not "reasonably & adequately staffed"

Provisions found in both bills

- All health care facilities to have patient safety plan including:
  - Patient safety committee
  - Multidisciplinary teams to conduct ongoing implementation of evidence-based patient safety practices
  - Ongoing safety training of personnel

Provisions found in both bills

- Mandatory reporting of serious preventable adverse events
  - Defined as “a preventable adverse event that results in death or loss of a body part, or disability or loss of bodily function lasting more than seven days or still present at the time of discharge from the health care facility

Provisions found in both bills

- Voluntary, anonymous reporting of "near misses"
  - Defined as "an occurrence that could have resulted in an adverse event, but the adverse event was prevented"

Differences between Bills

- A50 requires facility to assure that patients or their families are informed of an adverse event
  - "Adverse event" defined in both bills as "an event that is a negative consequence of care that results in unintended injury or illness, which may or may not have been preventable."

Differences between Bills

- While both bills provide that documents, materials or information developed as part of a process of critical self-analysis &/or reported to the State are not discoverable in any civil, criminal or administrative action or proceeding,
  - ***A50 has several large exceptions***

Differences between Bills

- A50 excepts documents, info, &/or material in reports to the State (both voluntary and mandatory systems) that are :
  - included with the report, but developed, maintained, or existing separately
  - available from other sources if they are otherwise discoverable

Differences between Bills

- Under A50, all factual information on serious preventable adverse events is discoverable in civil suit brought by patient
  - even if it is contained in materials reported to the State or developed as part of a process of self-critical analysis

Summary

- S2174 approach more likely than A50 to promote improvements in patient safety
  - systems improvements to reduce errors require sharing information for analysis
  - extent of self-critical analysis and reporting unlikely to improve without adequate shielding from litigation
- DHSS will push for this approach to be enacted